JUL 12 2002

K020926

Section II

510(K) Summary

Company Information:

Epimed International, Inc.
PO Box 1128
Gloversville, NY 12078
(518) 725-0209
Contact: Christopher B. Lake
Manager of RA/QA

Date Prepared:

March 6, 2002

Trade Name:

Extension Set

Common Name:

Extension Set

Product Class/Classification:

Class II

Predicate Device(s):

Becton Dickinson Medical Systems Luer Lok™ Microbore Extension Set, Catalog # 385301

Abbott Hospital Products Microbore Extension Set, Catalog # 13360-48

Description:

The Extension Set is a device used to supplement Epimed's current line of regional anesthesia catheters. The Extension Set consists of flexible plastic tubing, a male luer lock fitting on one end and a female luer lock fitting on the other end. Extension sets will be provided as a sterile, single use, disposable devices. The Extension Set will be available in a variety of lengths ranging from 12" to 60".

Intended Use:

The Extension Set is intended for the conduction of fluids or medications.

Comparison to Predicate:

The Extension Set has similar physical and technical characteristics to the Luer-Lok™ Microbore Extension Set marketed by Becton-Dickonson Medical Systems and the Microbore Extension Set marketed by Abbott Hospital Products.

Non-Clinical Data:

Bench testing performed on the Extension Set to compare performance characteristics to the predicate device(s) confirmed that the performance of the Epimed Extension Set is similar to that of the predicate device(s). The devices were tested with regard to Fitting Bond Strength, Tubing Tensile Strength, Quantitative Flow, Qualitative Flow and Priming Volume.

Conclusion:

The testing performed and comparison to the predicate device(s) demonstrate that the Extension Set is safe and effective and is substantially equivalent to the predicate device(s).

Very truly yours,

Epimed International, Inc.

Christopher B. Lake
Manager of Regulatory Affairs/Quality Assurance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2002

Mr. Christopher Lake
Manager of RA/QA
Epimed International, Incorporated
141 Sal Landrio Drive
Johnstown, New York 12095

Re: K020926
Trade/Device Name: Extension Set, Models 1911-512
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: June 24, 2002
Received: June 27, 2002

Dear Mr. Lake:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020926

Device Name: Extension Set

Indications For Use:

The extension set is used to extend the length of another fluid or medication delivery device to provide continued fluid flow.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020926